



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/019,375	03/05/2002	Lawrence C. Smith	1051-1-020	6403
23565	7590	04/21/2006	EXAMINER	
KLAUBER & JACKSON 411 HACKENSACK AVENUE HACKENSACK, NJ 07601			CROUCH, DEBORAH	
			ART UNIT	PAPER NUMBER
			1632	
DATE MAILED: 04/21/2006				

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>		<b>Applicant(s)</b>	
	10/019,375		SMITH ET AL.	
	<b>Examiner</b>		<b>Art Unit</b>	
	Deborah Crouch, Ph.D.		1632	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on 08 February 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-18, 20-24 and 28-42 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-18, 20-24 and 28-42 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 26 October 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

Art Unit: 1632

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on February 8, 2006 has been entered.

The amendment filed February 8, 2006 has been entered. Claims 1-18, 20-24 and 28-42 are pending.

The rejection made under 35 U.S.C. § 112, first paragraph is withdrawn in view of applicant's amendments to the claims.

The rejection made under 35 U.S.C. § 112, second paragraph made in the office action mailed August 5, 2005 is withdrawn in view applicant's amendments to the claims.

The rejection made under 35 U.S.C. § 102(b) of claims 25-27 made in the office action mailed August 5, 2005 is withdrawn in view of applicant's cancellation of the claims.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1-18, 20-24 and 28-42 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by U.S. Patent 6,580,017 B1 issued June 17, 2003 (Echelard).

Art Unit: 1632

Echelard teaches methods for the production of reconstructed goat oocytes, reconstituted goat embryos, methods for the production of transgenic goat embryos, a method of cloning a goat, methods for producing transgenic goat embryos, and methods of cloning a goat comprising incubating goat oocytes to telophase II, and then further incubating the oocyte in the presence of cytochalasin B, enucleating the activated, telophase II oocyte by aspiration or microsurgery removing second polar body and surrounding cytoplasm (col. 19, lines 6-14, and 18-26), transferring a cultured goat fetal fibroblast which contains a DNA sequence encoding antithrombin III (col. 16, lines 19-25 and lines 42-44) into the perivitelline space of the enucleated oocyte (col. 19, lines 35-40), fusing the reconstructed embryo by electrofusion (col. 19, lines 48-52), culturing the reconstituted embryo to produce a transgenic embryo (col. 21, lines 22-24), which is then transferred to a surrogate mother goat to produce a transgenic goat offspring (col. 21, lines 25-27 and col. 22, line 52). Echelard teaches activation by electrofusion, ethanol, ionophore or serum (col. 13, lines 42-43 and col. 19, lines 14-16). Serum and ethanol were used to activate MII oocytes. Echelard also teaches the fibroblast donor cells were in one of G0 or G1 stage of the cell cycle (col. 8, lines 32-34). Further, Echelard teaches transgenic goat embryos, fetuses and offspring. Echelard teaches the production of cows, including transgenic cows by the method exemplified by the cloning of goats (col. 1, lines 34-36 and col. 13, 21-22). Thus, Echelard clearly anticipates the claimed invention.

Where, as here, the claimed and prior art products are identical or substantially identical, or are produced by identical or substantially identical processes, the PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his claimed product (*In re Ludtke*). Whether the rejection is based on "inherency" under 35 USC 102, on "prima facie obviousness" under 35 USC 103, jointly or alternatively, the burden of proof is the same, and its fairness is evidenced by the

Art Unit: 1632

PTO's inability to manufacture products or to obtain and compare prior art products. *In re Best, Bolton, and Shaw*, 195 USPQ 430, 433 (CCPA 1977) citing *In re Brown*, 59 CCPA 1036, 459 F.2d 531, 173 USPQ 685 (1972). The PTO does not have the means to determine if the presently claimed nonhuman transgenic embryo, transgenic fetus or transgenic offspring, claims 25-27, are identical to those disclosed in Echelard.

Applicant argues that Echelard teaching negative results in nuclear transfer methods where oocytes treated with ethanol in telophase failed to give viable embryos and fetuses (col. 22, lines 34 and 35). Applicant argues that Echelard does not teach or suggest enucleation of activated oocytes performed precisely when undergoing expulsion of the second polar body or after the second polar body has been expelled by the oocyte. Applicant argues Echelard does not teach ethanol activation of in vivo matured oocytes. These arguments are not persuasive.

In the specific example, ethanol treated oocytes did not yield live born goats. However, ethanol was used to activate in vivo matured oocytes that arrested prior to second polar body formation/extrusion. The present specification activates MII oocytes, first polar body containing, with ethanol and permits them to continue to telophase II (page 9, step 1). Thus, Echelard's disclosure of ethanol treatment as an activating agent is enabled. Table 2 clearly shows that telophase enucleated oocytes yield a twin pregnancy and the birth of 2 live-born kids. Since applicant's method and Echelard's method are the same, it is not understood how applicant's method could be enabled but not Echelard's method. If the method steps are the same, the methods are both enabled. The difference between the two methods is not seen. Further, Echelard teaches activation of in vitro matured oocytes by serum (col. 13, lines 42-43). Ethanol activation is not a requirement of each claim, it is noted.

Art Unit: 1632

An oocyte in telophase is inherently activated, that is the telophase oocyte is in the process of extruding its second polar body. This is the definition of telophase. From applicant's arguments it is not clear when they believe enucleation is taking place in Echelard. However, if telophase means the second polar body is being extruded then any enucleation, such as that of Echelard, has to be occurring at that time. Further, Echelard teaches "... oocytes which demonstrate a protrusion in the plasma membrane, usually with a spindle abutted to it, up to extrusion of the second polar body are considered to be oocytes in telophase" (col. 14, lines 32-35). Thus Echelard teaches enucleation precisely when the oocyte is undergoing expulsion of the second polar body. In addition, Echelard specifically teaches enucleation of telophase II oocytes by aspirating the extruded second polar body (telophase spindle) (col. 19, lines 21-25). Thus, Echelard does teach both enucleation of activated oocytes precisely when undergoing expulsion of the second polar body or after the second polar body had been expelled. The claims require a "mammalian host oocyte" be activated by artificial means. There is no requirement that the oocyte be in vivo or in vitro matured, only be activated. The activation by Echelard of oocytes that did not undergo activation, regardless of the maturation type, by ethanol meets this limitation of the claimed invention.

Applicant argues that conceived their invention prior to November 1998, the priority of US Patent 6,580,017 (Echelard). Declarant Smith provides a copy of a research grant proposal as evidence of earlier conception. These arguments are not persuasive.

A declaration under 37 CFR 1.131 does not overcome a rejection under 35 U.S.C. § 102(e) as applicant's claims and Echelard's claims are to the same invention (see MPEP 706.02(b), "D" under 102(e)). Applicant is advised to review MPEP 2306 and determine if an interference proceeding would be proper and file the appropriate request.

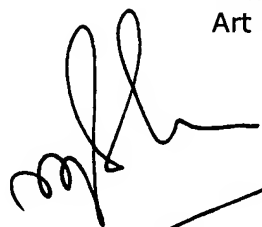

Art Unit: 1632

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah Crouch, Ph.D. whose telephone number is 571-272-0727. The examiner then normally be reached on M-Fri, 7:30 AM to 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla, Ph.D. can be reached on 571-272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Deborah Crouch, Ph.D.  
Primary Examiner  
Art Unit 1632

April 17, 2006